



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,776	08/05/2003	Frederick G. St. Goar	37531-501C01 (17315-00200)	1704
78169 7590 05/13/2009 MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, PC ATTN: PATENT INTAKE CUSTOMER NO. [EVALVE] ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER BACHMAN, LINDSEY MICHELE	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 05/13/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/635,776	Applicant(s) ST. GOAR ET AL.	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43,51,52 and 54-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43,51,52 and 54-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1-22-09, 4-2-09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed 22 January 2009.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 43, 51, 52, 54-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup (US Patent 5,593,424) in view of Stevens et al. (US Patent 5,769,812).

Claim 43: Northrup'424 teaches a method of modifying a heart valve (column 1, lines 8-12) that includes placing anchors (10) directly on the annulus (see Figures 2-4 and column 5, lines 17-48), coupling a filament to the anchors (column 5, line 59 to column 6, line 8) and tightening the filament to modify the annulus and reduce regurgitation (column 6, lines 3-8). Northrup is silent regarding the method of accessing the heart valve and therefore does not teach advancing the device from a femoral venous location through the body's vasculature to access the heart.

Stevens'812 teaches that it was old and well known to access the heart via a femoral venous location for the purpose of repairing a valve because this reduces patient morbidity and mortality (column 4, lines 5-67; Figure 7). The device of Stevens'812 is capable of penetrating the annular portion of the heart, as shown in Figure 7. It would have been obvious to one of ordinary skill in the art to modify the method taught by Northrup'424 with the percutaneous access method taught by

Art Unit: 3734

Stevens'812 in order to provide the advantage of decreasing recovery time and the risk of complications.

Claim 51, 52: Northrup'424 teaches that the anchors contain a suture (column 5, line 17 to column 6, line 8).

Claim 54: Stevens'812 shows that it is known to cross the interatrial septum (see Figure 4).

Claim 55, 57, 58: Northrup'424 teaches that the method can be performed on a mitral valve (column 4, lines 34-46) and tightening the filament circumferentially tightens the annulus to reduce regurgitation in the mitral valve (column 5, lines 35-48).

Claim 56: Stevens'812 teaches use of a guide catheter (10) with a catheter (75).

Claim 59, 60 and 61: Northrup'424 teaches that tightening the filament comprises circumferentially tightening the filament by plicating portions of the annulus (column 5, lines 16-45).

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

Art Unit: 3734

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./

Examiner, Art Unit 3734

/TODD E MANAHAN/

Supervisory Patent Examiner, Art Unit 3734